UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/279,275	07/22/94	WEINER H	101016104US1

HM12/1012

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EXAMINER	
VANDER VEGT,F	
ART UNIT	**PAPER NUMBER**
1644	66

DATE MAILED: 10/12/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/279,275	Weiner et al
Examiner	**Group Art Unit**
F. Pierre VanderVegt	1644

. ☒ Responsive to communication(s) filed on *Jul 10, 2000*.

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), ~~or thirty days, whichever is longer~~, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *9, 11-13, 15, and 20-26* is/~~are~~ pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *9, 11-13, 15, and 20-26* is/~~are~~ rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

This application is a file-wrapper-continuation of application S.N. 07/460,352, which is a continuation-in-part of application S.N. PCT/US88/02139, which is a continuation-in-part of application S.N. 07/065,734.

Claims 1, 9, 11-13, 15 and 20-26 are currently pending in this application.

1. In view of the amendment filed July 10, 2000, the following rejections are maintained.

Claim Rejections - 35 U.S.C. § 112

2. Claims 1, 9, 11-13, 15 and 20-26 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It was stated previously: "Applicant contends that Applicant has included evidence of enablement with the response filed September 30, 1999, however no such evidence can be found, only Applicant's continued argument. Applicant makes a series of statements but fails to substantiate them with citations pertaining to the appropriate art or with an expert affidavit. Accordingly, the arguments can not be considered evidence and the rejection stands for the same reasons stated previously in paper #56, mailed August 25, 1998."

Applicant's arguments filed July 10, 2000 have been fully considered but they are not persuasive.

Applicant argues that previous patents to the Applicant and coworkers provide sufficient evidence for the enablement of the instantly claimed invention. Applicant is reminded, however, that each application is examined on its own merits in regard to the invention claimed IN THAT APPLICATION. Since the instant invention is not the same invention as that claimed in any of the other applications, the instantly claimed invention was never examined on its merits in any of the other applications. Therefore, the allowed claimed inventions of the recited patents can not be relied upon as evidence of enablement of the instant invention.

3. Claims 1, 9, 11-13, 15 and 20-26 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It was stated previously: "Briefly, the claims are drawn to the treatment of autoimmune disease by oral or enteral immunization of a mammal with an autoantigen specific for the autoimmune disease being treated or an autoimmune response suppressive fragment thereof. The effectiveness of treating a response to an autoantigen is dependent on several factors, the most critical of which is whether the therapy can be used to treat an ongoing autoimmune response or whether it is only effective prophylactically (Tisch et al, U on form PTO-892, page 437, column 2, last paragraph in particular). Typically, an autoimmune disease is diagnosed only after significant tissue damage has already occurred. Administration of antigen after pathogenic T cells have been activated may have an exacerbating effect on the disease, rather than a tolerogenic one. Another problem during the treatment of autoimmune diseases is determinant spreading during the course of the disease. The Tisch et al reference also teaches that "the high degree of specificity required for the process of clonal deletion/anergy may be limiting when dealing with diseases such as MS, IDDM, and RA, in which there are responses to several autoantigens [...] and the critical inciting autoantigen(s) is not known" (page 437, third full paragraph of column 3 in particular). The breadth of Applicant's claims are such that they include treatment of autoimmune diseases with peptides which have not been characterized, on the basis of terming them "autoimmune response suppressive fragments." The claims confer no degree of specificity with which one of skill in the art could relate the treating peptide with a particular condition. Therefore the art would predict that it would be counterproductive to treat autoimmune disease patients with autoantigens or fragments, as such treatment would more likely than not exacerbate the ongoing immune response. The autoimmune diseases encompassed by the claims each have etiologies which are different from the others, each has different target autoantigens, and the risk of incidence of each of these is associated with a unique human lymphocyte antigen haplotype. Further there has been no disclosure of the autoantigens which are associated with immune attack in each of these conditions. Further, the working examples provided in the specification discloses only the prophylactic treatment of otherwise normal animals for a set time period prior to the occurrence of autoimmune events which are the result of a known initiating antigen. The artisan is not provided sufficient information by the instant specification in order to practice the method of the instant claimed invention over a long-term course for treatment of an ongoing autoimmune disease and may result in exacerbation rather than relief.

Pharmaceutical therapies are unpredictable for the following reasons; (1) the protein may be inactivated before producing an effect, i.e. such as proteolytic degradation, immunological inactivation or due to an inherently short half life of the protein; (2) the protein may otherwise not reach the target area because, for example, (a) the protein may not be able to cross the mucosa, (b) the protein may be adsorbed or absorbed by fluids, cells and tissues where the protein has no

effect; and (3) other functional properties, known or unknown, may make the protein unsuitable for in vivo use, i.e. may produce adverse side effects prohibitive to the use of such treatment. See MPEP 608.01(p).

In view of the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims, it would take undue trials and errors to practice the claimed invention and this is not sanctioned by the statute."

Applicant argues that the instantly claimed invention is enabled for the treatment of ongoing autoimmune disease, not just prophylactic treatment, based upon exemplification in the instant specification, notably examples 2, 10 and 11. The argument is not persuasive. Example 2 does show administration of oral MBP after immunization of the subject rats. However, at +2, +5 and +7 days post-immunization, the oral tolerization protocol began at the time the autoimmune response was first developing. It is well known in the art that in the Lewis rat, the first EAE attack does not begin until about 9-12 days post-immunization. This exemplification does not address determinant spreading because, at 2 days after immunization, such events have likely not begun in the animal.

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Papers related to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The fax phone number for official documents to be entered into the record for Art Unit 1644 is (703)305-3014.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to F. Pierre VanderVegt, whose telephone number is (703)305-6997. The Examiner can normally be reached Tuesday through Friday and odd-numbered Mondays (on year 2000 366-day calender) from 6:30 am to 4:00 pm ET. A message may be left on the Examiner's voice mail service. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ms. Christina Chan can be reached at (703)308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist, whose telephone number is (703)308-0196.

F. Pierre VanderVegt, Ph.D.
Patent Examiner
Technology Center 1600
October 6, 2000

CHRISTINA Y. CHAN
SUPERVISORY PATENT EXAMINER
GROUP ~~1800~~ 1640